

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known	
		Application Number	TBA
		Filing Date	November 20, 2003
		First Named Inventor	Angela Solito et al.
		Group Art Unit	TBA
		Examiner Name	TBA
Sheet 1 of 4	Attorney Docket Number	005284.00226	

U.S. PATENT DOCUMENTS					
Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
AR ↓		US-5,169,774	12/1992	Frankel et al.	
		US- 6,137,899	10/2000	Lee et al.	
		US- 3,786,801	01/1974	Satorius	
		US- 6,413,228	07/2002	Hung et al.	
		US- 6,494,859	12/2002	Love et al.	
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FOREIGN PATENT DOCUMENTS						
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³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Sheet 2 of 4

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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
AR		Sartorius, Breast Fluid Cells Help In Early Cancer Detection, JAMA, Vol. 224(6), pp 823-827, 1973	
		Papanicolaou et al, "Exfoliative Cytology of the Human Mammary Gland and Its Value in the Diagnosis of Cancer and Other Diseases of the Breast", Cancer, pp 377-409, March/April, 1958	
		Petrakis, "Physiological, biochemical, and cytological aspects of nipple aspirate fluid", Breast Cancer Research and Treatment, Vol. 8, pp 7-19, 1986	
		Petrakis, "Studies on the epidemiology and natural history of benign breast disease and breast cancer using nipple aspirate fluid", Cancer Epidemiology, Biomarkers and Prevention, Vol. 2, pp 3-10, Jan/Feb 1993	
		Petrakis, "Nipple Aspirate Fluid in Epidemiological Studies of Breast Disease", Epidemiologic Reviews, Vol. 15, pp 188-195, 1993	
		Sauter et al, "Nipple aspirate fluid: a promising non-invasive method to identify cellular markers of breast cancer risk", British Journal of Cancer, Vol. 76(4), pp 494-501, 1997	
		Imayama et al, Cancer, Vol. 78, pp 1229-1234, 1996	
		Love & Barsky, Breast-duct endoscopy to study stages of cancerous breast disease, Lancet, Vol. 348, pp 997-999, 1996	
		Goodson WH & King EB, Chapter 4: Discharges and Secretions of the Nipple, The Breast: Comprehensive Management of Benign and Malignant Diseases, 2 nd Ed., Vol. 2, Bland & Kirby eds. W.B. Saunders Co., Philadelphia, PA, pp 51-74, 1998	
		Wrensch et al, Breast Cancer Incidence in Women with Abnormal Cytology in Nipple Aspirates of Breast Fluid, American Journal of Epidemiology, Vol. 135 (2), pp 130-41, 1992	
		Wrensch et al, Breast Cancer Research and Treatment, "Factors associated with obtaining nipple aspirate fluid: Analysis of 1428 women and literature review", Vol. 15, pp 39-51, 1990 Sauter et al, Prostate-Specific Antigen Levels in Nipple Aspirate Fluid Correlate with Breast Cancer Risk, Cancer Epidemiology, Biomarkers & Prevention, Vol. 5(12), pp 967-70, 1996	
		Wrensch et al, Breast Fluid Cholesterol and Cholesterol B-Epoide Concentrations in Women with Benign Breast Disease, Cancer Res., Vol. 49, pp 2168-2174, 1989	
		King et al, Nipple Aspirate Cytology for the Study of Breast Cancer Precursors, JNCL, Vol. 71(6), pp 1115-1121, 1983	
		Sartorius et al, Cytologic Evaluation of Breast Fluid in the Detection of Breast Disease, J. Natl Cancer Inst, Vol. 59, pp 1073-1080, 1977	

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AR		Frykberg and Masood Copeland EM 3d. Bland KI., (Ductal carcinoma in situ of the breast) Surgery, Gynecology & Obstetrics, Vol. 177(4), pp 425-40, 1993	
		King et al, Cytometry, "Analytic Studies of Foam Cells From Breast Cancer Precursors", Vol. 5, pp 124-130, 1984	
		King et al, A.J.C.P., "Cellular Composition of the Nipple Aspirate Specimen of Breast Fluid", Vol. 64, pp 728-738, 1975	
		Masood et al, The Missing Link: A "Pap Smear" For Early Breast Cancer Detection and Prevention, The Breast Journal, Vol. 5, pp 1-2, 1999	
		Petrakis et al, Studies on the Epidemiology and Natural History of Benign Breast Disease and Breast Cancer Using Nipple Aspirate Fluid, Cancer Epidemiology, Biomarkers and Prevention, Vol. 2, pp 3-10, 1993	
		Sartorius et al, Cytologic Evaluation of Breast Fluid in the Detection of Breast Disease, NCI, Vol. 59, pp 1073-1080, 1977	
		Fabian et al, J. Cellular Biochemistry, Biomarker and Cytologic Abnormalities in Women at High and Low Risk for Breast Cancer, Vol. 17G, pp 153-160, 1993	
		Porter-Jordan and Lippman, "Overview of the biological markers of breast cancer", Hematology/Oncology Clinics of North America, Vol. 8(1), pp 73-100, 1994	
		Sauter et al, Prostate-Specific Antigen Levels in Nipple Aspirate Fluid Correlate with Breast Cancer Risk, Cancer Epidemiology, Biomarkers & Prevention, Vol. 5(12), pp 967-70, 1996	
		JIN, Zhang et al. "Study of Tumor Markers in Mammary Ductal Lavage for Early Detection of Breast Carcinoma. I. Chinese Tumor Clinical Medicine, Vol. 23, Issue 6, pp. 381-385, 1996 (with English Translation attached)	

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AR		Sartorius, O.W. et al., "Cytologic Evaluation Of Breast Fluid In The Detection Of Breast Disease", Journal Of The National Cancer Institute, Vol. 59, No. 4, pp 1073-1080, 1977	..
		King, E. B. et al., "Analytic Studies Of Foam Cells From Breast Cancer Precursors", Cytometry, Vol. 5, No. 2, pp 124-130, 1984	
		Sneige, Nour et al., "Fine needle aspiration cytology of ductal hyperplasia with and without atypia and ductal carcinoma in situ", Human Pathology, Vol. 25, No. 5, pp 485-492, 1994	
		Love, Suan M. et al., "Breast-duct endoscopy to study stages of cancerous breast disease", Lancet (North American Edition), Vol. 348, No. 9033, pp 997-999, 1996	
		King, E. B. et al., "Cellular Composition Of The Nipple Aspirate Specimen Of Breast Fluid Part 1 The Benign Cells, American Journal of Clinical Pathology, Vol. 64, No. 6, pp 728-738, 1975	
		Porter-Jordan, Kathleen et al., "Overview of the biologic markers of breast cancer", Hematology-Oncology Clinics of North America, Vol. 8, No. 1, pp 73-100, 1994	
		Evron, Ella et al., "Detection of breast cancer cells in ductal lavage fluid by methylation-specific PCR", Lancet (North American Edition), Vol. 357, No. 9265, 2001	

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